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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,828	12/09/2003	Ian D. Faulkner	PZ9918 CON	4379

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Amerhsam Health, Inc.
101 Carnegie Center
Princeton, NJ 08540

EXAMINER

GILBERT, SAMUEL G

ART UNIT PAPER NUMBER

3735

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,828	FAULKNER ET AL.	
	Examiner	Art Unit	
	Samuel G. Gilbert	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-10,12,13,15,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-10,12,13,15,18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langton et al(5,460,592) in view of Bolea(5,863,790).

Langton teaches a method of making and sterilizing a seed train. The applicant's attention is invited to column 2 lines 60-64, showing the method of heating and subsequently cooling to make the seed train semi-rigid. Column 3 lines 10-13 that teaches the device can be stiffened and sterilized at the same time. Column 6 lines 1-3 show a temperature range of 150-185 C for 1 hour to stiffen the material. The examiner is taking element -13- as a closed container. Sleeve -28- is gas impermeable. I-125 is set forth in column 5, lines 14-21. It is inherent that the seeds are free of moisture. Regarding claim 12 – the heat is dry heat. The applicant's attention is invited to column 6, line 1. However Langton et al does not teach a time of at least two hours for sterilization. It is old and well known in the medical art that when using dry heat for sterilization the typical time period is at least two hours as shown by Bolea column 1 lines 39-42. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use a time period of at least two hours for dry heat

sterilization for the device of Langton et al as set forth in Bolea to ensure the device is properly sterilized.

Claims 9 and 19 - the seeds may be I-125 and Pd-103, column 5 lines 5-21.

Claim 10 – It is the examiner's position that the seeds of Langton et al are inherently free of moisture but if they would include at the beginning of the dry heat sterilization process the seed would be free of moisture at the end of the dry heat sterilization process.

Claim 14 – the applicant's attention is invited to the embodiment of figure 23.

Claim 18 - it is the examiner's position that the elements are isotropic, unless specifically designed to provide a dose distribution, which is not isotropic, the radiation distribution of most seeds known in the medical arts are isotropic. The applicant has provided no evidence that the seeds of Langton et al are out of the ordinary and therefore are considered to be isotropic.

Claims 7 and 15 - the devices after sterilization are shipped the end user. The end user would need to know what specific radiation train is contained in the sterile package to decide which seed train to use. Labels are well known in the medical arts to provide end users with the information they need. The examiner is taking official notice that end user package labels are well known in the medical arts and would have been obvious to use with the container of Langton et al. to provide the end user with the required information.

Claim 8 - when using an autoclave it is known to sterilize more than one instrument at the same time. It would have been obvious to one of ordinary skill in the

art at the time the invention was made to sterilize more than one device at a time as a duplication of elements which is within the skill of one of ordinary skill in the art.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kan 6,106,455 in view of the combination of Langton et al (5,460,592) and Bolea(5,863,790) as applied to claim 1 above. Kan teaches sterilizing loose seeds with steam. Langton and Bolea teach using dry heat in the range claimed for the time claimed by the applicant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use dry heat sterilization with the device of Kan as a substitution of functionally equivalent elements as taught by Langton et al and Bolea.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 7-10, 12, 13, 15, 18 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,692,426 in view of Langton et al(5,460,592) and Bolea (5,863,790). Faulkner et al teaches an method and product as claimed but does not set forth the particular radioactive seeds used and the time of two hours required for dry heat sterilization. Langton sets forth the claimed seeds and Bolea sets forth a time of at least two hours for dry heat sterilization. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use the particular seeds taught by Langton et al and the particular time for sterilization set forth by Bolea with the method/product claimed in Faulkner et al. as an ordinary design expedient of selecting any known particular elements out of all known elements in the absence of showing any criticality in the exact seeds or sterilization time used.

Response to Arguments

In the first paragraph on page 5 of the applicant's remarks the applicant argues that Bolea teaches dry heat sterilization in a temperature range of approximately 180°C or higher for at least two hours. The examiner agrees that this is what Bolea teaches. The applicant goes on to argue that the applicants claim 1 requires the radioactive seeds are subjected to dry heat at a temperature of at least 140°C for a minimum of 2 hours to effect sterilization. The examiner also agrees claim 1 includes such a limitation. The applicant goes on to argue that Bolea does not teach or suggest using a

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temperature below 180°C to effect sterilization, again the examiner agrees. The applicant concludes that therefore the temperature and time requirements of Independent claim 1 would not have been obvious. The examiner disagrees for the following reasons;

The temperature range of claim 1 is at least 140°C this includes 140°C to an unstated upper limit T_{limit} which one would no longer use the temperature for dry heat sterilization. Bolea sets forth a range of temperature for dry heat sterilization as "approximately 180°C or higher". This includes 180°C to the same T_{limit} as set forth above. Therefore, the temperature ranges overlap from 180°C to T_{limit} . The examiner agrees that Bolea does not teach dry eat sterilization between the temperatures of 140°C to about 180°C, but does teach the claimed range from 180°C to T_{limit} .

On page 6, the applicant argues that one of ordinary skill in the art would not seek to improve Langton et al by increasing the sterilization time to two hours from the heating time of 1 hour set forth in the example of Langton et al in column 6 lines 1 and 2.

The examiner disagrees and would like to point out that the example in column 6 lines 1 and 2 of Langton only set forth a time required for stiffening the strand and while Langton et al sets forth that stiffening and sterilization may be completed at the same time this example does not set forth the time required for sterilization much less teach away from the at least two hours required for dry heat sterilization. It is the examiner's position that because the generally accepted length of time for dry heat sterilization is at

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least two hours, as set forth in Bolea column 1 lines 40-43 that one of ordinary skill in the art would recognize that the example set forth by Langton et al would require at least an additional hour of dry heating to effectively dry heat sterilize the sources.

In the second paragraph on page 7, the applicant argues Langton et al. discloses sterilizing a seed train in one hour. The applicant does not point to any different location for this teaching so the examiner assumes the applicant is relying on the example as previously discussed and again will point out that the example as set forth only talks about stiffening the seed strand. Langton et al does not set forth any specific time require for heat sterilization.

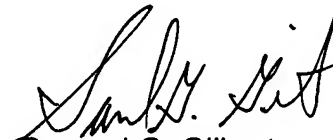
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Samuel G. Gilbert
Primary Examiner
Art Unit 3735

sgg